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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/980,697

08/14/2002

Ajay Kumar Luthra

16230-8677

8586

21888 7590 11/30/2005

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT

PAPER NUMBER

1618

DATE MAILED: 11/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/980,697

Applicant(s)

LUTHRA ET AL.

Examiner

Micah-Paul Young

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment of Papers Received: Amendment/Response dated 9/15/05.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 39,41,43, 45, and 47 are rejected under 35 U.S.C. 102(b) as anticipated by the teachings of Honda et al (JP 4080735595). The claims are drawn to a polymeric material incorporating a biguanide compound into its' polymer chain. The claims recite that the biguanide is chemically bound to the polymer via various possible linkages including urea and amine linkages.
3. Honda teaches an antimicrobial polymer comprising a polymer having in its chain a biguanide group and a polydimethylsiloxane chain (abstract). The resulting polymer is used for surface treating natural and synthetic materials to impart antimicrobial properties to the material. The reference is silent however to the specific linkages and bonds created by this polymer chain creating. According to applicant's specification (example 4), polydimethylsiloxane when combined with a biguanide compound results in a copolymer terminating in isocyanate groups, which result in substituted urea linkages. Therefor, though the reference is silent to the specific reactive sites and linkages. With these aspects in mind it is the position of the Examiner that the disclosures of the Honda reference anticipate the instantly claimed invention.

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4. Claims 39-66 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over the disclosures of Sawan et al (USPN 5,817,325 hereafter '325). The claims are drawn to a polymeric material incorporating a biguanide compound into its' polymer chain. The claims recite that the biguanide is chemically bound to the polymer via various possible linkages including urea and amine linkages.

5. The Sawan reference teaches an antimicrobial polymeric device comprising biguanide compounds (abstract, col. 8, lin. 23-68). The synthetic polymers include rubbers and thermoplastic deformable polymers such as polyurethanes, polyesters, polysulfone and polyisoprene. Other polymeric materials include organic materials such as polyamides, polycarbonate, polyacrylates, and celluloses. Non-polymeric materials that are modified by the biocides of the inventions include woods, papers, metals and cloths (col. 7, lin. 45-65). The organic material comprises groups such as epoxy, amine, hydroxyl, halogen, alkyl or alkoxy silyl (col. 9, lin. 1-8). The multifunction groups include isocyanate, epoxides, acid chlorides, acid anhydrides and carboxylic acids (col. 9, lin. 10-23). The polymers of the invention are incorporated into medical devices such as catheters, and intraocular lenses (col. 12, lin. 26-38). The biguanides include chlorhexidine and polyhexamethylene (col. 8, lin. 65-67). The polymers are blended in a process that includes a polymerization step (examples). The reference is silent to the specific chemical bonds, however the polymers of the '325 comprise the same functional groups as those of applicant. It is the position of the Examiner that barring a showing of unexpected result the polymers of the '325 patent would inherently comprise the chemical binding links of the instant claims given the identical components. With these things in mind, it is the position of the Examiner that the '325 patent anticipates the claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 39-66 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over the disclosures of Sawan et al (USPN 5,817,325 hereafter '325).

As discussed above the '325 patent discloses antimicrobial polymeric material. Also as discussed above the reference is silent to the specific links between the polymer and the biocidal compounds. However the '325 patent discloses identical polymers and functional groups that would result in the chemical bonds and linkages recited in the claims. It is the position of the Examiner that the polymer of the '325 patent would inherently possess these linkages. The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the

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same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences.

See Ex parte Phillips, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

9. With these things in mind it would have been obvious to follow the disclosures and suggestions of the art in order to impart an antimicrobial property onto a polymeric surface and/or matrix. It would have been obvious to follow these disclosures and teachings with an expected result of a non-leaching biocidal polymeric material.

Response to Arguments

10. Applicant's arguments with respect to claims 39-66 have been considered but are moot in view of the new ground(s) of rejection.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

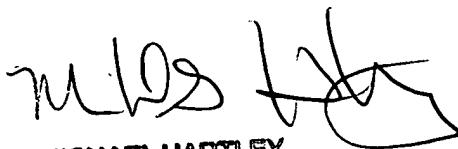
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MP Young

Micah-Paul Young
Examiner
Art Unit 1618


MICHAEL HARTLEY
PRIMARY EXAMINER